

§ 203.50

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(1) The name, address, and telephone number of the licensed practitioner (or donating charitable institution);

(2) The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and

(3) The date of the donation.

(f) Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

(g) Each recipient charitable institution shall conduct, at least annually, an inventory of prescription drug sample stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug sample inventory discrepancies and reconciliation problems shall be investigated by the charitable institution and reported to FDA.

(h) A recipient charitable institution shall store drug samples under conditions that will maintain the sample's stability, integrity, and effectiveness, and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

(i) A charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.

Subpart E—Wholesale Distribution

§ 203.50 Requirements for wholesale distribution of prescription drugs.

(a) *Identifying statement for sales by unauthorized distributors.* Before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller shall provide to the purchaser a statement identifying each prior sale, purchase, or trade of such drug. This identifying statement shall include:

(1) The proprietary and established name of the drug;

(2) Dosage;

(3) Container size;

(4) Number of containers;

(5) The drug's lot or control number(s);

(6) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and

(7) The date of each previous transaction.

(b) The drug origin statement is subject to the record retention requirements of § 203.60 and must be retained by all wholesale distributors involved in the distribution of the drug product, whether authorized or unauthorized, for 3 years.

(c) *Identifying statement not required when additional manufacturing processes are completed.* A manufacturer that subjects a drug to any additional manufacturing processes to produce a different drug is not required to provide to a purchaser a statement identifying the previous sales of the component drug or drugs.

(d) *List of authorized distributors of record.* Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record.

(1) Each manufacturer's list of authorized distributors of record shall specify whether each distributor listed thereon is authorized to distribute the manufacturer's full product line or only particular, specified products.

(2) Each manufacturer shall update its list of authorized distributors of record on a continuing basis.

(3) Each manufacturer shall make its list of authorized distributors of record available on request to the public for inspection or copying. A manufacturer may impose reasonable copying charges for such requests from members of the public.

EFFECTIVE DATE NOTE: At 64 FR 67756, Dec. 3, 1999, § 203.50 was added, effective Dec. 4, 2000. At 65 FR 25639, May 3, 2000, the effective date for § 203.50 was delayed until Oct. 1, 2001. At 66 FR 12851, Mar. 1, 2001, § 203.50 was further delayed until Apr. 1, 2002. At 67 FR 6646, Feb. 13, 2002, the effective date was further delayed until April 1, 2003. At 68 FR 4912, Jan. 31, 2003, the effective date was further delayed until Apr. 1, 2004.